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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/068,559

Applicant(s)

WILLSON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23, 50, 76 and 97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50 and 76 is/are allowed.
- 6) ☒ Claim(s) 1-23 and 97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 97 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al.(JP 09-105747).

The reference of Yamamoto et al. discloses a sensor array (1) that includes a supporting member (2) and a plurality of sensing elements (120,80,60,45,30) coupled to the supporting member (2) wherein the sensing elements comprise a plurality of different shapes (See Figure 2). Each sensing element has a different predetermined shape and each is responsive to different analytes. The sensing elements undergo a spectroscopic change when interacting with an analyte in a liquid sample. In the absence of further positively recited structural language, the color change of the sensing elements of the reference of Yamamoto et al. is considered to meet the claim limitation “undergo a spectroscopic change” since the instant application includes color changes of the sensing element to be encompassed by the disclosed invention. For example, See pages 27-28, “pH Sensing Experiment”, of the instant specification which is drawn to a visual

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color change. Also see pages 10-11 of the instant specification which discloses that optical changes can be made visually using a microscope.

3. Claim 97 is rejected under 35 U.S.C. 102(e) as being anticipated by Bodenhamer (US 6,051,388).

The reference of Bodenhamer discloses a sensor array that includes a supporting member (polymer film) and a plurality of sensing elements coupled to the supporting member wherein the sensing elements comprise a plurality of different shapes (See Figure 7). Each sensing element has a different predetermined shape and each is responsive to different analytes. The sensing elements undergo a spectroscopic change when interacting with an analyte in a liquid sample. In the absence of further positively recited structural language, the color change of the sensing elements of the reference of Bodenhamer is considered to meet the claim limitation "undergo a spectroscopic change" since the instant application includes color changes of the sensing element to be encompassed by the disclosed invention. For example, See pages 27-28 of the instant specification "pH Sensing Experiment" which is drawn to a visual color change. Also see pages 10-11 of the instant specification which discloses that optical changes can be made visually using a microscope.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-7, 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Campbell et al.(US 4,703,017) and Howard, III et al.(US 5,408,535).

The reference of Yamamoto et al. discloses a sensor array (1) that includes a supporting member (2) and a plurality of sensing elements (120,80,60,45,30) coupled to the supporting member (2) wherein the sensing elements comprise a plurality of different shapes (See Figure 2). Each sensing element has a different predetermined shape and each is responsive to different

analytes. The sensing elements undergo a spectroscopic change when interacting with an analyte in a liquid sample. In the absence of further positively recited structural language, the color change of the sensing elements of the reference of Yamamoto et al. is considered to meet the claim limitation “undergo a spectroscopic change” since the instant application includes color changes of the sensing element to be encompassed by the disclosed invention. For example, See pages 27-28, “pH Sensing Experiment”, of the instant specification which is drawn to a visual color change. Also see pages 10-11 of the instant specification which discloses that optical changes can be made visually using a microscope.

Claim 1 differs by reciting that the system includes a light source and a detector positioned such that light passes from the light source to the sensing elements and onto the detector during use.

The reference of Campbell et al. discloses that there is ample motivation in the art to substitute or verify visual observation of the a test substrate using instrumentation (See column 15, lines 44-57).

The reference of Howard, III et al. discloses that it is known in the art to automate the reading of a test strip by using a light source (15,13) and detector system (12,33) for detecting the signal produced by the interaction of the analyte with the sensing elements during use.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a light source and detector system as suggested by the reference of Howard, III et al. with the sensor device of the primary reference of Yamamoto et al. for the known and expected result of reducing the imperfections associated with the use of the naked eye when comparing colors (See column 1, lines 15-49, of Howard, III et al.) and/or for the known and expected result

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of replacing visual detection with the use of instrumentation as is suggested by the reference of Campbell et al.

With respect to claim 2, the reference of Howard, III et al. discloses the use of a white light source (15).

With respect to claim 3, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ other known light sources, such as LED or lasers, based merely on the specifics of the reagents employed in the sensing element while maintaining the efficiency of the detection system.

With respect to claims 4 and 5, the reference of Howard, III et al. discloses the use of a CCD camera and filters (See column 5, lines 23-31).

With respect to claim 6, the use of filters to remove background light and/or excitation light is conventional in the art and would have been obvious for the known and expected result of improving the signal-to-noise ratio of the detection system.

With respect to claim 7, the reference of Yamamoto et al. discloses that the support member can be made of a polymer (See paragraph [0017] of the machine translation).

With respect to claim 9, the sensing element is positioned at the surface of the supporting member (See Figure 2).

With respect to claim 15, the support member (2) is a rigid material and the sensing elements are disposed on a surface of the support member (See Figure 2).

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8. Claims 8, 11-14, 17, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Campbell et al.(US 4,703,017) and Howard, III et al.(US 5,408,535) taken further in view of Wohlstadter et al.(US 6,066,448).

The combination of the references of Yamamoto et al., Campbell et al. and Howard, III et al. has been discussed above.

The above claims differ further because they recite the use of polymers and receptors when describing the sensor support member and sensing elements.

The reference of Wohlstadter et al. discloses the use of a sensing array device (See Figures 5A and 5B) wherein each reagent zone includes different binding specificities (receptors) (See column 11, lines 12-55). The reference also discloses that the support member can be made of a polymer material (See column 12, lines 5-12). Furthermore the reference discloses a number of means in which to form the array of binding sites on the support member. The list of techniques includes integrating the receptors into a porous matrix prior to polymerization or gelation (See column 15, lines 3-48).

In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to manufacture the test strip of the modified primary reference using the known techniques taught by the reference of Wohlstadter et al. for the known and expected result of providing an alternative means recognized in the art for providing an array of sensing elements on a support member such that the sensing elements can be exposed to a sample fluid.



Note the specific receptors and/or reagents employed would have been clearly within the level of one having ordinary skill in the art for the known and expected result of employing specific reagents dependent upon the target analyte that is to be detected.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Campbell et al.(US 4,703,017) and Howard, III et al.(US 5,408,535) taken further in view of Mauze et al.(US 6,379,969).

The combination of the references of Yamamoto et al., Campbell et al. and Howard, III et al. has been discussed above.

Claim 16 differs by reciting that the support member includes a well with the sensing element within the well.

The reference of Mauze et al. discloses that it is known in the art to provide a sensing element array in the form of a support member with sensing elements on the surface thereof (See Figure 2) or the support member can be a well plate with the sensing elements within the wells (See Figure 5).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a support member that includes wells for the known and expected result of providing an alternative means recognized in the art to achieve the same result, supporting a sensor array to be contacted with a fluid sample. The use of wells would prevent cross contamination between the test zones in the array.

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10. Claims 10, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Campbell et al. (US 4,703,017), Howard, III et al.(US 5,408,535) and Wohlstadter et al.(US 6,066,448) taken further in view of Walt et al.(US 5,512,490).

The combination of the references of Yamamoto et al., Howard, III et al., Horikami and Wohlstadter et al. has been discussed above.

While the prior art discussed above discusses the use of a polymer material for forming the sensing element, the instant claims recite the use of a polyethylene glycol polymer.

The reference of Walt et al. discloses that when forming a sensing substrate as shown in Figure 1, it is known to employ polyethylene glycol polymer as a means for immobilization of the detection reagents (See column 27, lines 11-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimum polymer to employ when immobilizing the test reagents or receptors as suggested by the prior art while maintaining the efficiency of the detection system.

#### ***Allowable Subject Matter***

11. Claims 50 and 76 are allowed.

#### ***Response to Arguments***

12. Applicant's arguments and associated amendments to claim 50, see pages 9-11, filed 15 Sept. 2004, with respect to claim 50 over the reference of Heizmann have been fully considered and are persuasive. The rejection of claim 50 has been withdrawn.

13. Applicant's arguments and associated amendments to claim 76, see pages 11-13, filed 15 Sept. 2004, with respect to claim 76 over the reference of Yamamoto have been fully considered and are persuasive. The rejection of claim 76 has been withdrawn.

14. Applicant's arguments and associated amendments to claim 97, see page 13, filed 15 Sept. 2004, with respect to claim 97, have been fully considered but they are not persuasive.

Applicants argue that claim 97 defines over the reference of Yamamoto et al. because the sensing elements of the device of Yamamoto et al. undergo color changes rather than spectroscopic changes.

Applicants' comments are not found to be persuasive because the claim language "spectroscopic changes" has been interpreted to include color changes as evidenced by Applicants' own disclosure. The instant application includes color changes of the sensing element to be encompassed by the disclosed invention. For example, See pages 27-28, "pH Sensing Experiment", of the instant specification which is drawn to a visual color change. Also see pages 10-11 of the instant specification which discloses that optical changes can be made visually using a microscope.

15. Applicant's arguments and associated amendments to claim 1, see pages 13-15, filed 15 Sept. 2004, with respect to claim 1 over the reference of Walt have been fully considered and are persuasive. The rejection of claim 1 over the reference of Walt has been withdrawn.

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16. Applicant's arguments and associated amendments to claim 97, see pages 15-16, filed 15 Sept. 2004, with respect to claim 97, have been fully considered but they are not persuasive.

Applicants argue that claim 97 defines over the reference of Bodenhamer et al. because the sensing elements of the device of Bodenhamer et al. undergo colorimetric changes rather than spectroscopic changes.

Applicants' comments are not found to be persuasive because the claim language "spectroscopic changes" has been interpreted to include color or colorimetric changes as evidenced by Applicants' own disclosure. The instant application includes color or colorimetric changes of the sensing element to be encompassed by the disclosed invention. For example, See pages 27-28, "pH Sensing Experiment", of the instant specification which is drawn to a visual color change. Also see pages 10-11 of the instant specification which discloses that optical changes can be made visually using a microscope. Also see page 10, lines 14-25, of the instant specification.

17. Applicant's arguments with respect to claims 1-23 over the combination of the references of Yamamoto et al. in view of Howard, III et al. and Horikami have been considered but are moot in view of the new ground(s) of rejection. Note claim 1 was amended to remove references to the determination of the shape using the detection system.

With respect to the combination of the references of Yamamoto et al. and Howard, III et al., Applicants argue that the combination of a visual device with the system of Howard et al. would not be within the purview of one having ordinary skill in the art. The Examiner has cited the reference of Campbell et al. which clearly evidences that one of ordinary skill in the art

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would have been motivated to supplement and/or replace visual determinations with instrumentation for making the same determination.

Applicants' comments concerning the additional references in combination with the references of Yamamoto et al. and Howard, III et al. do not question the obviousness of the further combinations. Applicants merely state that the additional references do not make up for the deficiencies previously discussed with respect to the combination of the references of Yamamoto et al. and Howard, III et al.

### *Conclusion*

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

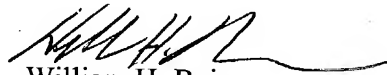
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB